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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,904	02/17/2004	Lorraine D. Butlin	IMIN.P-033-2	7556
21121	7590	03/03/2005	EXAMINER	
OPPEDAHL AND LARSON LLP P O BOX 5068 DILLON, CO 80435-5068			PORTNER, VIRGINIA ALLEN	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 03/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/780,904

Applicant(s)

BUTLIN ET AL.

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/19/2005
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15, 16 and 18-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15 and 16 is/are allowed.
- 6) ☒ Claim(s) 18-20, 26-37 is/are rejected.
- 7) ☒ Claim(s) 21-25, 31 and 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/19/2005
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claims 15-16, 18-37 are pending.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Allowable Subject Matter

1. Claims 15 and 16 define over the prior art of record and are therefore allowed.
2. Claims 21, 23-25 are objected to a depending from a rejected base claim.

Rejections/Objections Withdrawn

3. Claims 31-32 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, is herein withdrawn in light of the amendment of the claims to no longer depend from a canceled claim.
4. Claims 20 and 33-34 are objected to because of the following informalities have been obviated in light of the modifications and amendments made to the claims.
5. Claims 21, 23-25, 29, 31-32 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is herein withdrawn in light of the amendment of the claims and traversal set forth in Applicant's response.

Rejections/Objections Maintained

6. Claims 22 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, is herein maintained for reasons of record in paper number 08262004.
7. Claims 18-20, 33-37 rejected under 35 U.S.C. 102(b) as being anticipated by O'Daly et al (US Pat. 5,391,272), is maintained for reasons of record in paper number 08262004 and responses set forth below.
8. Claims 18-20, 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Overlie, I et al (1999), is maintained for reasons of record in paper number 08262004 and responses set forth below.
9. Claims 18, 26-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Birken et al (US Pat. 6,521,416), is maintained for reasons of record in paper number 08262004 and responses set forth below.
10. Claims 18, 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Niccoli et al (1996) as evidenced by Costagliola et al (1994, reference 13, incorporated by reference), is maintained for reasons of record in paper number 08262004 and responses set forth below.

Response to Arguments

11. Applicant's arguments filed December 3, 2004 have been fully considered but they are not persuasive.

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11. The objection to claims 22 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, is traversed on the grounds the examiner's reading of the claims "The Examiner appears to be arguing that something that binds to both chains cannot also be an antibody that differentiates between isoforms of FSH." The objection is further addressed by stating that "the application shows two specific antibodies, both of which were induced against the combination of alpha and beta chains, which have different binding specificity."

12. It is the position of the examiner that gonadotropin isoforms are based upon carbohydrate epitopes not the amino acid sequence of the peptide chains. The amino acid sequences of each gonadotropin alpha and beta chain do not change, but the carbohydrate glycosylation patterns chains do change. Antibodies that only bind to the alpha and beta peptide chains (as recited in claim 21 "alpha and beta chains", would not detect different isoforms of the same gonadotropin. For this reason claim 22 was objected to, as only the amino acid chains are detected in both claims 21 and 22, and the first antibody pair of claim 21 detects total FSH and so does the antibody pair of claim 22 detect Total FSH, claim 22 is not further limiting of claim 21 as now claimed.

The antibody pair used to traverse the objection, is not commensurate in scope with what is now claimed; amendment of claim 22 to recite the antibody pair that detects different carbohydrate isoforms, specifically the Deposited antibodies of claims 15 and 16, could obviate this objection.

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Please Note: The examiner is reading the instantly claimed invention of independent claims 18 and 33 to be directed to a genus of methods and devices that assay a human female sample, the sample being one which can and does contain a plurality of gonadotropin forms.

The instant disclosure at page 5, paragraph 4, lines 13-21, sets forth the genus of gonadotropins to be assayed as a family (page 5, line 20) of molecules that exist in different forms (see page 5, lines 20-21). Each member of the family comprise a common alpha subunit (see page 5, line 19), and each different form (see page 5, lines 20-21) evidences a different beta subunit.

The pending genus claims measure any one or more of the members of the family of gonadotropins, each member of the family representing a different form of gonadotropin.

Claims 18, paragraph (b) and claim 33, paragraph (a) require:

- a. the first assay to measure a gonadotropin form that is independent of menopausal state, and this assay may measure any member of the gonadotropin family

Claim 18, paragraph (b), second subparagraph and claim 33, paragraph (b) require

- b. the second assay to measure a gonadotropin form that is indicative of the a menopausal state, which may be the **same or different member** of the family of gonadotropins, as long as the gonadotropin is assayed contemporaneously (assay on the same sample or on taken from the same individual within a defined period of time after the first sample was obtained). The claims do not require the measurement of the same gonadotropin in the first and second assays, but must measure different forms of gonadotropin, the forms including the different beta subunits of the gonadotropin family.

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13. The rejection of claims 18-20, 33-37 under 35 U.S.C. 102(b) as being anticipated by O'Daly et al (US Pat. 5,391,272) is traversed on the grounds that O'Daly et al measure two different gonadotrophins and that is not what is claimed.

14. It is the position of the examiner that based upon the fact that the family of gonadotropins set forth at page 5, lines 13-21, includes a plurality of molecules, each molecule being member of the family existing as different form of gonadotropin, and the fact that female samples contain a plurality of gonadotropin forms, O'Daly et al still anticipates the instantly claimed invention, as now claimed. The instantly claimed method and device require assaying two gonadotropin forms, which includes two members of the family of gonadotropins, each member being a different form based upon a different beta subunit, but evidencing a common alpha subunit in order to be a member of the family of gonadotropins (see discussion above "Please Note").

15. The rejection of claims 18-20, 26-29 under 35 U.S.C. 102(b) as being anticipated by Overlie, I et al (1999) is traversed on the grounds that Overlie measure two different gonadotrophins and that is not what is claimed.

16. It is the position of the examiner that based upon the fact that the family of gonadotropins set forth at page 5, lines 13-21, includes a plurality of molecules, each molecule being member of the family existing as different form of gonadotropin, and the fact that female samples contain a plurality of gonadotropin forms, Overlie et al still anticipates the instantly claimed invention, as now claimed. The instantly claimed method and device require assaying two gonadotropin forms, which includes two members of the family of gonadotropins, each member being a

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different form based upon a different beta subunit, but evidencing a common alpha subunit in order to be a member of the family of gonadotropins (see discussion above "Please Note")

17. The rejection of claims 18,26-30 under 35 U.S.C. 102(e) as being anticipated by Birken et al (US Pat. 6,521,416) is traversed on the grounds that Birken et al (US Pat. 6,521,416) measure two different gonadotrophins and that is not what is claimed.

18. It is the position of the examiner that based upon the fact that the family of gonadotropins set forth at page 5, lines 13-21, includes a plurality of molecules, each molecule being member of the family existing as different form of gonadotropin, and the fact that female samples contain a plurality of gonadotropin forms, Birken et al (US Pat. 6,521,416) still anticipates the instantly claimed invention, as now claimed. The instantly claimed method and device require assaying two gonadotropin forms, which includes two members of the family of gonadotropins, each member being a different form based upon a different beta subunit, but evidencing a common alpha subunit in order to be a member of the family of gonadotropins (see discussion above "Please Note").

19. The rejection of claims 18, 26-27 under 35 U.S.C. 102(b) as being anticipated by Niccoli et al (1996) as evidenced by Costagliola et al (1994, reference 13, incorporated by reference) is traversed on the grounds that Niccoli et al (1996) measure two different gonadotrophins and that is not what is claimed.

20. It is the position of the examiner that based upon the fact that the family of gonadotropins set forth at page 5, lines 13-21, includes a plurality of molecules, each molecule being member

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of the family existing as different form of gonadotropin, and the fact that female samples contain a plurality of gonadotropin forms, Niccoli et al (1996) still anticipates the instantly claimed invention, as now claimed. The instantly claimed method and device require assaying two gonadotropin forms, which includes two members of the family of gonadotropins, each member being a different form based upon a different beta subunit, but evidencing a common alpha subunit in order to be a member of the family of gonadotropins (see discussion above "Please Note").

Newly amended claims 31-32/New Grounds of Rejection/Objection

Claim Objections

21. (Amended) Claims 31-32 are objected to because of the following informalities: Claims 31-32 recite the phrase "configured such that the such that when"; the claims recite an extra transitional phrase. Appropriate correction is required.

Claim Rejections - 35 USC § 112

22. The term "give rise to a similar indication" in claims 31-32 is a relative term which renders the claim indefinite. The term "give rise to a similar indication" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

23. How similar or different the indications are to be considered to be similar is not defined in the claims. What degree of similarity or difference the first and second assays must be in their indications is not distinctly claimed. When the first and second assays produce a similar or nearly identical indication, the resulting assays would not meet the requirement of claim 18 from

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which they now depend which requires the indications to be “different (see claim 18, subparagraph (b), last paragraph)”. How a result can be similar and different at the same time is not clearly, nor distinctly claimed based upon the recitation of the relative term “similar in the claims.

Conclusion

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
February 22, 2005



MARK NAVARRO
PRIMARY EXAMINER